Unit 1. Treatment of Adverse Reactions

Objective: Using the provided information, identify the principles in relation to the task procedure for treating adverse reactions to medication and vaccines.

STS: 14.b (5)(a), 14.b (5)(b). **These items are tested on the end-of-course written test.**

Performance Qualification: 14.b (5)(a), 14.b (5)(b). **These items are trained and verified by the assigned 4N0X1A using the QTP's listed below.**

Qualification Training Package (QTP):

Vol. 12, Module 4, Management of Adverse Reactions Following Immunizations

001. Anaphylaxis

Anaphylaxis (an'a-fi-lak'sis) One form of a Type I allergic or hypersensitivity reaction to an allergenic antigen. Symptoms include:

> Feeling of impending doom, metallic taste in mouth, pruritis, urticaria, angioedema, itching of eyes nose, or throat, rhinorrhea, sneezing, difficulty swallowing, pharyngeal or laryngeal swelling, chest tightness, wheezing, SOB, nausea, vomiting, abdominal or uterine cramping, low blood pressure, rapid heart rate, arrhythmia's, convulsions, or death.

Anaphylaxis results from an antibody response. It is an immediate and often life threatening event in which massive release of mediators triggers a sequence of events in target organs throughout the body, resulting in a variety of symptoms. These symptoms range from mild to life threatening. Manifestation may include merely complaining of "a feeling of doom" to classic clinical symptoms of airway distress. All organs and systems in the body are subject to anaphylaxis.

People die from anaphylaxis! Fortunately, in the clinical setting, anaphylaxis is 99.7% preventable when all the appropriate protocols are followed. Less than one percent of the patients you see are potential candidates to have an allergic reaction.

Remember, one preventable death is one too many. Each and every patient must be asked if they have any allergies to food or medication.

In 1997 there were 15 anaphylactic reactions to flu shots in Air Force facilities, two were serious. Is it an acceptable standard to only ask a patient receiving a Flu shot "Are you allergic to eggs"? Or a person receiving an MMR? Most vaccines have multiple components. The most appropriate question to ask a patient is, "Do you have any allergies to food or medications?" Surprisingly enough, patients who have had a serious allergic reaction to a vaccine in the past will show up at the immunization clinic for a second immunization of the same vaccine when it is due. The rationale is they heard the vaccine has changed or they were instructed to get the immunization by the "mobility person." Also, be aware, these individuals will not offer the information on a mobility line just prior to deployment. Another question that must be asked, for obvious reasons, is "Have you ever had a reaction

Recognition and Treatment of Anaphylaxis

Recognition and treatment of anaphylaxis is a primary responsibility for all those who administer injectables of any kind (See 4N0X1A Qualification Training Package (QTP), Vol. 12, Module 4). Being prepared is 99% of the treatment! In an environment where the patient load is often overwhelming, just knowing that

anaphylaxis may occur at any moment is part of the battle. Start each day by checking your emergency equipment, supplies, and emergency duress system. ALWAYS make sure you have continuos PHYSICIAN COVERAGE before administering any type of immunization. Knowing the signs and symptoms that your patient may exhibit as an anaphylactic reaction is the most important step in the initiation of treatment. Treatment protocols must be clearly posted in areas of high risk, such as Immunization Clinics.

Target Organ	**Mild**	**Moderate**	**Severe**
General Status	malaise; sense of illness	vague sense of illness	greater malaise
Skin	hives; erythema, tingling warm sensation, itching	generalized urticaria; flushing, generalized pruritis, periorbital edema	cyanosis, pallor
Upper Respiratory Trac	nasal congestion sneezing, rhinorrhea conjunctivitis, fullness in mouth or throat	profuse congestion or rhinorrhea	periorbital edema, obligatory mouth breathing
Upper Airway	fullness in mouth or throat	edema of: tongue, larynx pharynx, hoarseness	stridor, completely occluded airway
Lower Airway	cough	bronchospasm, dyspnea cough, wheezing	severe dyspnea, hypoxia respiratory arrest
Gastrointestinal Tract	cramping	nausea, vomiting increased peristalsis	dysphasia, intense abdominal cramping diarrhea
Cardiovascular System	tachycardia	hypotension, syncope	coronary insufficiency cardiac arrhythmia's
Central Nervous System	anxiety	intense anxiety, confusion	Seizures, coma

Protocols may vary from clinic to clinic but the

INITIAL TREATMENT IS ALWAYS THE SAME:

Table 5.1.

- **SUMMON HELP**.
- *All clinics will have an established duress system. This may range from an actual Emergency Room distress signal to a distress code via the overhead public announcement system. Regardless how help is summoned, it must be unmistakable by those tasked to respond*.
- **POSITION YOUR PATIENT IN THE SUPINE POSITION.**
- **ADMINISTER EPINEPHRINE 1:1000 AQUEOUS SUBCUTANEOUSLY**.
- *Normally, dosage is according to weight. In an emergency situation, age and weight standardizes this dose. For adults the standard dose is .30 cc and for a child, < 60 pounds is .15cc.*
- **ABC ASSESSMENT AND AIRWAY MAINTENACE**.
- **VITAL SIGNS**
- *You must obtain a blood pressure, respiration and a pulse. This base line is critical. Epinephrine and/or progressing anaphylaxis can and will directly impact these vital signs. Physician's decisions on further treatment will be greatly influenced by these vitals. Vital signs should be reaccomplished every five minutes until directed otherwise. Effects of epinephrine may last up to thirty minutes. Patents will experience a variety of collateral symptoms. The symptoms can range from nausea to anxiety. As with any other type of shock the vascular system is subject to collapse.*
- **OXYEGN THERAPY (IF NEEDED)**
- *Ensure the patient has an established airway and provide oxygen via a simple facemask (10 LPM) or nasal cannula (6 LPM).*

Epinephrine

Now that we know that epinephrine is the drug of choice, what is epinephrine? How does it work?

Epinephrine is a normally occurring hormonal secretion produced by the adrenal medulla that stimulates both Alpha and Beta-adrenergic receptors and its release is brought about by the stimulation of the sympathetic division of the autonomic nervous system. What does this mean?

Epinephrine is adrenaline and causes both,

Vasoconstriction and bronchodialation.

What causes the airway compromise in an anaphylactic reaction is the mast cells releasing histamines, causing the smooth muscles (Beta 1 receptors) of the air way to constrict, potentially closing off the airway. Epinephrine relaxes these muscle cells (bronchodilation) thus allowing the airway to remain patent. Epinephrine also stimulates the beta 2 receptors in the smooth muscles surrounding the heart. The effects on this type of muscle are increased activity and the alpha receptors found in blood vessels causing them to tighten (vasoconstriction). This increased activity increases blood pressure and heart rate. This information should help you understand how the epinephrine you give is affecting the patient, which in turn will help give the patient insight on side effects.

Occasionally multiple doses of injected epinephrine are not sufficient to turn around severe hypersensitivity reactions. Local protocols will determine which drugs are administered and when. It is your responsibility to be completely familiar with these protocols and act as a facilitator in the management of these patients. Even with this said basic EMT skills are an essential tool. Always remember your ABC's

All Immunization technicians must be well-versed in administering epinephrine and managing anaphylactic patients.

Epinephrine is supplied in various ways. The two most common are the pre-filled tubex and the ampule. The tubex is a full CC and calibrated into 10^{th}'s. The ampule is 2cc's and requires a separate syringe to draw up and give.

002. Vasovagal

Now that you have a realistic appreciation for the inherent danger of injectables lets discuss the **MOST COMMON** post injection adverse reaction, Vasovagal reaction or fainting (syncope). This can happen to any patient at any time regardless of past experiences.

Once again you must ask the patient, "*Have you ever had any problems with previous injections?*"

Each patient must be assessed for potential of having an adverse reaction when receiving an immunization. Is their behavior appropriate for the situation or is

there a high anxiety level? Did the adult patient have to bring a companion to “help” them through this? If there ever is a doubt about a patient’s potential to faint, sit them down. There is a far less distance to the floor from a siting position.

Vasovagal syncope is caused by stimulation of the vagal nerve, which controls many of our internal organs parasympathetic functions. It may be stimulated by pain or simply by a startling or shocking situation. The most important effect is to slow the heart rate, which leads to a fall in blood pressure, which may lead to loss of consciousness.

Syncope is comprised of a generalized weakness of muscles with loss of postural tone resulting in the inability to stand upright and progressing to a loss of consciousness. Inevitably, this occurs while the patient is in the upright postural position, standing. A “bad feeling” usually precedes loss of posture or consciousness. The patient then may become confused, see spots, or complain of dim vision or nausea. Occasionally the contents of the stomach are expelled. Another classic, visible sign is clammy skin with pallor. The patient may turn an ashen gray and break into a cold sweat.

The MOST dangerous aspect of a vasovagal episode is sustained injury in a fall.

The depth and duration of the episode may vary. Some patients merely sweat profusely while other will lose consciousness completely and demonstrate clonic jerks. The first time this is witnessed by a medical technician it can easily be interpreted as a seizure. It may also be quite frightening if you are the only medical support available. Due to this form of shock, the pulse may be difficult to obtain, in a vasovagal syncope episode the pulse becomes extremely slow, and the blood pressure will normally present extremely low. Occasionally respiration’s become imperceivable or irregular. This episode can last anywhere from a few seconds to half an hour.

This may be very difficult to differentiate from anaphylaxis. A slow steady pulse is consistent with anaphylaxis, a weak rapid thready pulse is consistent with anaphylaxis. Any time a patient has an unobtainable BP after an immunization especially if there are other symptoms consistent with anaphylaxis such convulsions you should consider the use of epinephrine.

With any episode a patient will need to be evaluated by a providers soon as available and again prior to departure. As a general rule, “If any patient has a change in status while under your care a higher echelon of care must evaluate them.” Initial treatment is always the same:

Table 5.2

- **ELEVATION OF THE LEGS**
- **LOOSEN ANY RESTRICTIVE CLOTHING**.
- In severe episodes the head should be turned to the side to prevent the patient from choking on vomits or their tongue**.**
- **ONCE THE PATIENT REGAINS CONSCIOUSNESS,** or begins to get their bearings there may be an urge to stand. Many patients are quite confused when they become aware of their surroundings and are unaware of the proceeding that led them to be lying in the floor.
- Embarrassment is usually an issue and privacy must be a concern.
- Once the patient has returned to a level of consciousness you are comfortable with, have them sit up for a few minutes. Once you allow them to stand be prepared for a second episode. If enough time is allowed this does usually not occur. Occasionally patients will still feel uneasy. Sit them down immediately and wait until these feelings pass. Remember, since the patient's status has changed there must be an evaluation and a note made in the patient's medical record.
- *Patients should never be allowed to go from prone to standing directly (Remember, this is a type of shock and dilation of blood vessels has occurred).*

003. Vaccine Adverse Event Reporting System

What is VAERS?

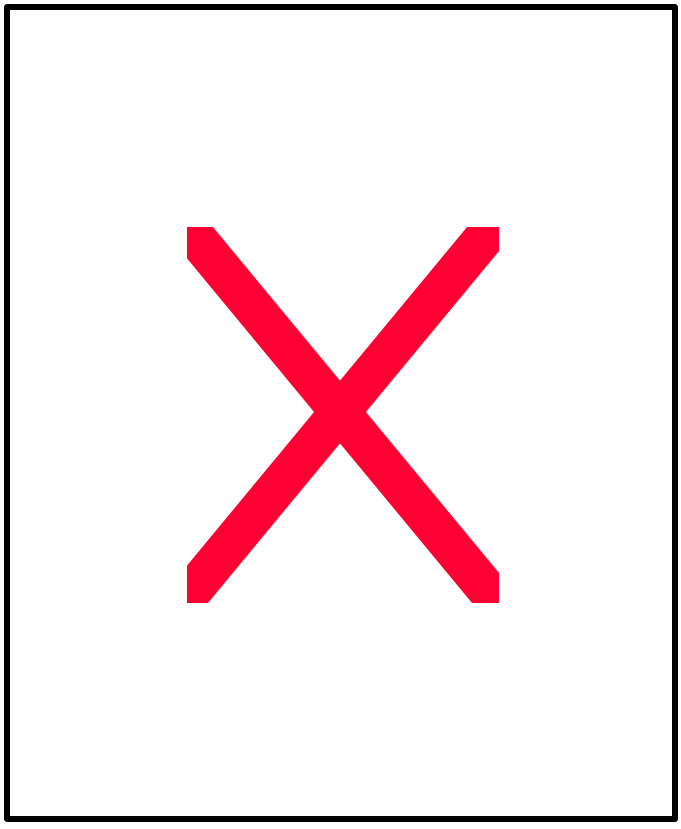
The National Childhood Vaccine Injury Act (NCVIA) of 1986 mandated the reporting of certain adverse events following vaccination to help ensure the safety of vaccines distributed in the United States. This Act led to the establishment of the Vaccine Adverse Event Reporting System (VAERS) in November 1990 by the Department of Health and Human Services. VAERS provides a database management system for the collection and analysis of data from reports of adverse events following vaccination. VAERS is co-managed by the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA).

Who can report to VAERS?

Any one can report to VAERS. VAERS reports are usually submitted by health care providers, vaccine manufacturers, and vaccine recipients (or their parents/guardians). Patients, parents, and guardians are encouraged to seek the help of a health care professional in reporting to VAERS.

Why should I report to VAERS?

Each report provides information that is compiled to assess vaccine safety. Complete and accurate reporting of post-vaccination events supplies public health professionals with the information they need to ensure the safest strategies of vaccine administration.



How do I report to VAERS?

A VAERS report form, pre-addressed to VAERS and postage-paid, is used to report pertinent information, including a narrative description of the adverse event. To review a sample copy of the VAERS report form, see pages 3005-3006 of the 1997 Physician's Desk Reference (PDR). You may submit your report on photocopies of the form. ***For report forms or assistance in filling them out call VAERS at 1-800-822-7967.***

What events should be reported to VAERS?

Although NCVIA only requires reporting by health care providers and vaccine manufacturers of the post-vaccination adverse events outlined in the **Reportable Events Table**. (http://www.fda.gov/cber/vaers/eventtab.htm). Although it not critical that you be familiar with every aspect on this table it is very important that you are aware of it and can locate it should you need it. VAERS encourages all reporting of any clinically significant adverse event occurring after the administration of any vaccine licensed in the United States.

FREQUENCY OF SERIOUS OUTCOMES ON VAERS REPORTS

(Jan. 1, 1991 - Dec. 31, 1996)

Type of Outcome	Number of Events	Percentage of All Serious Reports (N=8827)
Disability	1201	13.6%
Hospitalization	6707	76.0%
Extended Hospitalization	413	4.7%
Life Threatening	1226	13.9%
Death	1208	13.7%

A single VAERS report may report more than one serious outcome. The total number of serious events will exceed the total number of serious reports.

Approximately 15% of the reports reflect adverse events resulting in life-threatening illness, hospitalization, permanent disability, extended hospital stay, or death. The remaining 85% of the reports describe milder events such as fever, local reactions transient crying or mild irritability, and other less serious experiences.

The **Reportable Events Table** specifically outlines the post-vaccination events which must be reported. The need to report is also based on the amount of time which elapsed between the vaccination and the start of the event. ***A copy of the Table can be obtained by calling VAERS at 1-800-822-7967.***

The NCVIA requires the following events be reported:

1) Any event set forth in the **Reportable Events Table** that occurs within the time period specified.

2) Any event listed in the manufacturer's package insert as a contraindication to subsequent doses of the vaccine.

Other guidance for filling out a VEARS form for Active Duty can be found in AFJI 48-110. Anthrax differs form this and SG NOTAM 99-005 should be used when reporting adverse events to Anthrax vaccine. (This will be available in the Immunization Clinic)

004 Performance Qualification

After reviewing the end-of-unit review questions complete the attached Qualification Training Package. Verification of this training must be accomplished prior to taking the final examination.

Volume 12 **Module 4**

MANAGEMENT OF ADVERSE REACTIONS FOLLOWING IMMUNIZATIONS

SUBJECT AREA:	Immunization.
TASK(s):	Identify and initiate treatment of adverse reactions.
CFETP/STS REFERENCE(s):	14.b.(5)(a), (b).
EQUIPMENT REQUIRED:	Gloves, syringe, needle adequate for subcutaneous injection, 2X2 gauze, sharps container, epinephrine, 1:000 w/v, blood pressure cuff, stethoscope, duress system or emergency call bell, VEARS-1 form or Military Immunization Tracking System (MITS) access.
TRAINING REFERENCE(s):	Allergic Disease and Diagnosis and Management; Allergy Principles and Practice; Mosby's Textbook for Nursing Assistant's; The Lippincott Manual for Nursing Practice; AFJI 48-110; Immunizations and Chemoprophylaxis; MITS users guide; National Vaccine Injury Program; Vaccine Injury Table; Manufacturer's package insert.
REMARKS/NOTES:	Review steps of the process one-on-one with medical technician and/or nursing personnel skilled and verified in treating adverse reactions following immunizations.
OBJECTIVE:	The trainee will successfully demonstrate without error the performance aspects of treating adverse reactions following immunizations.

EVALUATION INSTRUCTIONS:

1. After the trainee has received instruction, allow sufficient practice on each part of the task.

2. The evaluator will **STOP** the procedure immediately and correct the trainee if performance could become detrimental to patient safety at any time.

3. Use the performance checklist to ensure all steps of the task are accomplished.

4. Document task competency upon completion of the evaluation in the trainee's OJT record. Initial evaluation should be documented in the CFETP. All recurring evaluations should be documented on AF Form 1098.

PERFORMANCE ITEM	SAT	UNSAT
KNOWLEDGE		
1. Differentiate between anaphylaxis and vaso-vagal		
2. Verbalize classic differences:		
a. Vasovagal: Signs and symptoms include, but are not limited to, cool clammy skin, high anxiety pre injection, syncope, and nausea slow steady pulse.		
b. Anaphylaxis: Signs and symptoms include, but are not limited to, respiratory distress, upper airway swelling, nausea, bowel cramps, diarrhea, uterine cramps (rare), and a feeling of impending doom, rapid thready pulse.		
3. Define anaphylaxis on a cellular level.		
4. Explain how epinephrine works.		
TREATMENT		
1. Get help (911, activate duress, etc.).		
2. Position patient in the supine position.		
3. Administer epinephrine 1:1000w/v (simulate):		
a. Over 60 lbs. = 0.30cc given SC.		
b. Under 60 lbs. = 0.15cc given SC.		
4. Assess patient for further intervention (ABCs).		
5. Obtain base line vital signs.		
6. Administer oxygen at 10 lpm.		
7. Attempt to obtain history from conscious patient.		
8. Explain normal physiological reactions of epinephrine to patient.		
9. Follow local protocols for anaphylaxis management.		
10. Monitor patient and assess vital signs every 15 minutes.		
11. Follow doctor's orders.		
ADMINISTRATIVE		
1. Verbalize circumstances that would indicate completing a VAERS-1.		
a. Any reaction listed in the Vaccine Injury Table.		
b. Any reaction-requiring medical attention or that is not listed in the manufacturer's package insert.		

2. Complete blocks 1 through 21 on VAERS-1. When using MITS, select "Adverse Reaction" menu and successfully navigate prompts.		
3. Verbalize where copies are distributed: a. Original to Department of Health and Human Services.		
b. Copy to HQ AFMOA/SGOP.		
c. Copy for clinic records.		
4. Properly document outpatient medical record, IAW AFJI 48-110. Documentation must include: a. Vaccine.		
b. Manufacturer and lot number.		
PERFORMANCE ITEM	SAT	UNSAT
c. Date of administration.		
d. Name and location of the medical facility.		
e. Type and severity of reaction.		
5. Annotate PHS 731 to ensure no further injections of offending vaccine.		
6. Verbalize recall initiation process: a. Suspend all vaccine in lot, but does discard.		
b. Notify Medical Logistics of suspect vaccine.		
c. Contact manufacturer for any previous reports.		
7. For active duty patients, advise attending physician if patient must be evaluated by an allergist for a permanent waiver/MEB IAW AFJI 48-110.		
FINAL RESULT:		

Trainee Signature/Date

4N0X1A Technician/Trainer Signature/Date

FEEDBACK: Using this checklist as a source of information, discuss the trainee's performance indicating strengths, weaknesses, suggested improvements, etc. If the trainee performed all steps of the task satisfactorily, document the results in the trainee's OJT record.

004. End of Unit Review

Instructions to the Trainee:

The following unit review questions are associated with the unit and the section that the answer can be found in. Read each question carefully and then look in the appropriate section for the correct answer. The degree of difficulty for each question is based on the proficiency level as identified in the STS. If used effectively, these review questions will prepare you for the formal test you will take through your facility or at the Medical Service Craftsman Course during your 7-level upgrade training.

EXAMPLE:

Unit 1. Principles of Immunizations

1. (002) A suspension of killed or live-attenuated microorganisms is referred to as?

   a. A Toxin
   b. A Vaccination
   c. A Deterrent
   d. An Immunization

Go to Unit 5 and review the section (002) until you find the appropriate response.

Begin the Unit Review!

Unit 5. Treatment of Adverse Reactions

1) (001) All organs and systems in the body are subject to anaphylaxis.

a. True
b. False

2) (001) Prior to administering any vaccine, what is the most appropriate question you should ask the patient?

a. Do you have any allergies?
b. Do you have any allergies to food or medications?
c. Do you have any allergies to medications?

3) (001) What is the appropriate dosage when administering epinephrine 1:1000 aqueous subcutaneously to a child < 60 pounds?

a. .15 cc
b. .30 cc
c. .50 cc

4) (001) Stimulation of which division of the autonomic nervous system cause the release of epinephrine?

a. Sympathetic division
b. Para-sympathetic division

5) (001) Epinephrine is referred to as adrenaline and causes _____?

a. Vasoconstriction/Bronchodilation
b. Vasodilation/bronchoconstriction

6) (001) What effect does epinephrine have on cardiac activity?

a. As epinephrine stimulates the receptor cells of the smooth cardiac muscle causing the heart rate and blood pressure to decrease.
b. As epinephrine stimulates the receptor cells of the smooth cardiac muscle causing the heart rate and blood pressure to increase.

7) (002) What is the most dangerous aspect of a vasovagal episode?

a. Injuries obtained from the fall.
b. Reduced blood flow to the brain.
c. Seizure activity.
d. None of the above.

8) (002) Why should you never allow a patient to go from the prone to standing position immediately following a vasovagal episode?

a. Bronchodilation has occurred.
b. Vasodilation has occurred.
c. Bronchoconstriction has occurred.
d. Vasoconstriction has occurred.

Please read the unit menu for Unit 2 and begin